# EXHIBIT B



UNIVERSITY OF WASHINGTON BOX 357160 SEATTLE, WA 98195 Customer ID: 1016

Certificate: 91-R-0001

Site: 001

UNIVERSITY OF WASHINGTON

Type: ROUTINE INSPECTION

Date: 26-JAN-2021

# 2.31(e)(3) Critical

# Institutional Animal Care and Use Committee (IACUC).

In a pilot study, researchers induced traumatic brain injury in young ferrets. This was part of an approved IACUC protocol. A total of ten ferrets were given three successive impacts to the skull at 24-hour intervals. However, rather than keeping the impact energy constant at each exposure as stated in the protocol, the group increased the impact energy between exposures. The research group did not have IACUC approval to make this significant change. Such oversight and approval is vital to ensure pain and distress are appropriately managed. The facility must ensure that a proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain a complete description of the proposed use of the animals. Corrected prior to the inspection.

# 2.33(b)(3)

## Attending veterinarian and adequate veterinary care.

A room containing 11 adult rabbits in building A was not checked over the weekend by staff. The staff had been notified that the room was in use. The rabbits were last checked on Friday afternoon (1/22/2021), and then not again until Monday morning (1/25/2021). The rabbits were assessed by a veterinarian on Monday (1/25/2021) and appeared healthy. The animals still had water and hay present. A daily observation is required to ensure that any issues are then conveyed to the attending veterinarian for assessment. Corrected prior to the inspection.



# 2.38(f)(1) Critical

## Miscellaneous.

An adult female pigtail macaque (#Z15297) was left in a trapping run for at least 12 hours without access to food or water. The animal was observed in the morning of 4/19/2020, but was not present in the compound in the afternoon. Although the staff looked in the trapping run, they did not see her. In addition, the staff believed the animal had been moved. The next morning, the animal was found in the trapping run. The macaque was moderately dehydrated, given immediate treatment, and had recovered by the next day. Physical harm or unnecessary discomfort may occur if handling of all animals is not done as expeditiously and carefully as possible. A specific plan with correction dates must be developed by 3/25/2021.

# 3.80(a)(2)(iii) Critical

## Primary enclosures.

During the overnight hours, an adult male pigtail macaque (#L11117) broke two locks on the connector between two side-by-side cages, and managed to push the cages apart. This event allowed both the male macaque and his cage mate, an adult female pigtail macaque (#T02319) to escape into the room. Both animals as well as several other nonhuman primates housed in the room were injured. A total of seven animals were injured. The injuries were mainly to the hands and fingers of the animals, and also included minor facial lacerations in the male pigtail macaque. All of the animals were treated by the attending veterinarian and recovered from their injuries. Enclosures that do not securely contain the nonhuman primates and prevent accidental opening of the enclosures can lead to injuries of the animals. A specific plan with correction dates must be developed by 3/25/2021.

No non-compliant items identified during this inspection.

This inspection and exit interview were conducted with



Additional Inspectors:

Michael Schnell, VETERINARY MEDICAL OFFICER



#### DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910
Home Page: http://grants.nih.gov/grants/olaw/olaw.htm

FOR EXPRESS MAIL.
Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

August 6, 2020

Re: Animal Welfare Assurance A3464-01 [OLAW Case 10Q]

Dr. David M. Anderson
Executive Director
Health Sciences Administration
University of Washington

(b) (4) Health Sciences Center, Box 356355
Seattle, WA 98195-6355

Dear Dr. Anderson,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your 30 July 2020 letter reporting a noncompliance with the PHS Policy on the Humane Care and Use of Laboratory Animals at the University of Washington. Your letter supplements the prompt telephone report received in this office on July 17, 2020. According to the information provided it is understood that at your Arizona facility, an enclosure underwent repairs to fix a broken door. When the animals were returned to the enclosure, the animals were able to remove a feeder due to a missing lock. A juvenile monkey was able to exit via the feeder hole. The animal crossed the facility and climbed towards the top of another enclosure where the breeder male pulled his arm through the enclosure mesh. The escapee sustained non-life-threatening injuries to multiple digits and the left arm. All injuries received prompt veterinary attention with appropriate analgesia. Due to the extent of the injuries sustained, the veterinary staff subsequently made the decision to amputate the arm. The animal has recovered.

Corrective and preventive actions: To mitigate future instances of missing locks, whenever a cage is empty, locks will remain in place on the enclosure doors and feeders. Staff have been reminded to check all locks every time they enter or exit an enclosure. Extra locks are available in the ante-room area of the building. No unallowable PHS funds were associated with this event.

OLAW believes that the corrective and preventive measures put in place by the University of Washington are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals for institutional self-monitoring and self-reporting. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse -S Morse -S

Digitally signed by Brent C. Morse -S

Date: 2020.08.06 16:14:27 -04'00'

Brent C. Morse, DVM Director Division of Compliance Oversight Office of Laboratory Animal Welfare

cc: IACUC contact

Obtained by Rise for Animals.

Uploaded to Animal Research Laboratory Overview (ARLO) on 11/16/2020

# W UNIVERSITY of WASHINGTON

HEALTH SCIENCES ADMINISTRATION
Office of the Executive Director

30 July 2020

Dr. Brent Morse <u>olawdco@od.nih.gov</u> Office of Animal Welfare, NIH 6700B Rockledge Drive, Suite 2500, MSC 6910 Bethesda, MD 20892

Re: D16-00292 (A3464-01), NHP Escape leading to injuries

Dear Dr. Morse:

This is a final report on a situation reported to OLAW by Dr. Stocking in a telephone call on 7/10/2020.

At the Arizona facility, an enclosure underwent repairs to fix a broken door. Prior to repairs, the resident animals were moved to a neighboring enclosure, the enclosure was sanitized, and all locks were removed. The animals were returned to the original enclosure and several hours later, the animals were able to remove a feeder due to a missing lock. A juvenile monkey was able to exit via the feeder hole. The animal crossed the facility and climbed towards the top of another enclosure where the breeder male pulled his arm through the enclosure mesh. The escapee sustained non-life-threatening injuries to multiple digits and the left arm. All injuries received prompt veterinary attention with appropriate analgesia. Due to the extent of the injuries sustained to the arm, the veterinary staff made the choice to amputate the arm 2 days later. The animal has recovered well and will be re-introduced to its social group in stages.

Corrective Action: To mitigate future instances of missing locks, whenever a cage is empty, locks will remain in place on the enclosure doors and feeders. Staff have been reminded to check all locks every time they enter or exit an enclosure. Extra locks are available in the ante-room area of the building.

The IACUC reviewed the incident at its July meeting and found no further action necessary. No unallowable PHS funds were associated with this event.

If you have questions regarding this situation or require additional information, please don't hesitate to contact me.

Sincerely,

(b) (6)

David M. Anderson, D.V.M. Executive Director, Health Sciences Administration Institutional Official

cc:

(b) (6) Dr. Kim Stocking

Box 356355 C414 Health Sciences Center Seattle, WA 98195-6355 206 543-7202

# Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)

**Sent:** Friday, July 31, 2020 7:49 AM

To: (b) (6)

Cc: OLAW Division of Compliance Oversight (NIH/OD)

Subject: RE: Final reports of non-compliances

Thank you for these reports, (b) (6) We will send responses soon.

Axel Wolff, M.S., D.V.M. Deputy Director, OLAW

From: (b) (6)
Sent: Thursday, July 30, 2020 2:56 PM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Cc: (b) (6) Kim Stocking <kstock@uw.edu>

Subject: Final reports of non-compliances

Please see the attached 3 final reports of noncompliance at the University of Washington. Let me know if you have any questions.

(b) (6)



<b>Count</b> 000011 000012	Scientific Name Canis lupus familiaris Saimiri sciureus
000016	Macaca fascicularis
000168 000313	Macaca mulatta Macaca nemestrina
000078	Oryctolagus cuniculus
000007	Sus scrofa domestica
000016	Meriones unguiculatus
000004	Mesocricetus auratus
000625	Total

Common Name DOG ADULT COMMON SQUIRREL MONKEY CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY RHESUS MACAQUE PIG-TAILED MACAQUE DOMESTIC RABBIT / EUROPEAN RABBIT DOMESTIC PIG / POTBELLY PIG / MICRO PIG MONGOLIAN GERBIL (COMMON
MONGOLIAN GERBIL (COMMON PET / RESEARCH VARIETY) SYRIAN / GOLDEN HAMSTER



#### DEPARTMENT OF HEALTH & HUMAN SERVICES

#### PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

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Bethesda, Maryland 20892-6910
Home Page: http://grants.nih.gov/grants/olaw/olaw.htm

FOR EXPRESS MAIL:
Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

Page 9 of 38

September 3, 2019

Re: Animal Welfare Assurance A3464-01 [OLAW Case 9U]

Dr. David M. Anderson
Executive Director
Health Sciences Administration
University of Washington

(b) (4) Health Sciences Center, Box 356355
Seattle, WA 98195-6355

Dear Dr. Anderson,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 21, 2019 letter responding to our request for additional information regarding allegations by (b) (6)

Specifically, we requested information regarding notes dated April 9, 2018 concerning "A15156 – 9 year old Indian Chinese rhesus" that was "found dead in cage cause of a large hematoma in the leg."

Based on your response to our questions we understand that the veterinarian that took the blood sample is well trained with over 40 years of experience in blood draws and that the animal received appropriate veterinary care for this unanticipated clinical outcome. Possible contributing factors include a clotting issue or having fragile vessels as a result of being a hybrid rhesus.

We thank the University of Washington for promptly addressing our request and providing further information. We appreciate your cooperation as Institutional Official regarding this unfortunate matter in particular and find no cause for further action by this office.

Sincerely,

(b) (6)

Brent C. Morse, DVM Director Division of Compliance Oversight Office of Laboratory Animal Welfare

cc: IACUC contact



## DEPARTMENT OF HEALTH & HUMAN SERVICES

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Bethesda, Maryland 20817
Telephone: (301) 496-7163
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September 3, 2019

(b) (6)		

Re: University of Washington

Dear (b) (6)

The Office of Laboratory Animal Welfare (OLAW) has completed its investigation regarding the allegations by (b) (6) concerning the University of Washington as contained in your June 25, 2019 email and attachment to our Office. Your email and the attachment were reviewed to determine OLAW's jurisdiction and potential noncompliance with the PHS Policy. Clarification regarding one item was requested from the university and another incident had previously been reported to our Office by the university and we had accepted the corrective and preventive measures. Other than that, one previously reported incident, OLAW has determined that none of the remaining items met the criteria for reporting to our Office.

OLAW will not review or investigate allegations unless specific incidents are cited that are noncompliant with the PHS Policy such as protocol noncompliance. The monitoring and refinement of the use of animals in research by the IACUC does not qualify as noncompliance.

OLAW shares your concern for the welfare of laboratory animals. We find no cause for further action by this office at this time.

Sincerely,

(b) (6)

Brent C. Morse, DVM Director Division of Compliance Oversight Office of Laboratory Animal Welfare National Institutes of Health

# HEALTH SCIENCES ADMINISTRATION Office of the Executive Director

August 21, 2019

Dr. Brent Morse <u>olawdco@od.nih.gov</u> Office of Animal Welfare, NIH 6700B Rockledge Drive, Suite 2500, MSC 6910 Bethesda, MD 20892

Re: D16-00292 (A3464-01), Case 9U

Dear Dr. Morse:

This report is the response to OLAW Case 9U described in the OLAW letter to the Institutional Official dated August 12, 2019.

The incident involved a 9 year old menseing female Indian Chinese hybrid rhesus macaque that underwent a routine sedated blood draw on 3/9/18 for evaluation of blood parameters prior to placement on a study. During the blood draw, the femoral artery was hit and a small hematoma formed. Pressure with ice was applied for 30 minutes and the animal closely monitored throughout that day. The animal appeared to be doing fine at the end of the day. The next morning, the animal was found dead in cage with bruising and a large hematoma present in the area of the blood draw. The necropsy report indicated that femoral arterial hemorrhage was the likely cause of death with no other significant lesions observed. It appears that this animal continued to slowly bleed overnight possibly due to a clotting issue or perhaps having fragile vessels as a result of being a hybrid rhesus. The veterinarian that took the blood sample is well trained with 40 years of experience in blood draws. This animal was not on a research study and received appropriate veterinary care.

The IACUC was informed of this adverse event at the harm benefit assessment subcommittee meeting on 4/9/18 and it was also discussed at the WaNPRC records review on 4/30/18. There was no corrective or preventive action taken as this was deemed an unanticipated clinical outcome that was most likely animal specific. Our OLAW Assurance does not include reporting to OLAW on unanticipated clinical outcomes when appropriate veterinary care has been given. This work was supported by a P51 grant.

If you have questions regarding this situation or require additional information, please don't hesitate to contact me.

Sincerely,

(b) (6)

David M. Anderson, D.V.M. Executive Director, Health Sciences Administration Institutional Official

cc:

(b) (6) Dr. Kim Stocking

Box 356355 C414 Health Sciences Center Seattle, WA 98195-6355 206 543-7202

# Morse, Brent (NIH/OD) [E]

From:

OLAW Division of Compliance Oversight (NIH/OD)

Sent:

Thursday, August 22, 2019 12:16 PM

To:

Kim Stocking; OLAW Division of Compliance Oversight (NIH/OD)

Cc:

David M. Anderson

Subject:

RE: Response letter to D16-00292 (A3464-01) OLAW Case 9U

Thank you for providing this information Dr. Stocking. We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: Kim Stocking [mailto:kstock@uw.edu]
Sent: Thursday, August 22, 2019 11:22 AM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Cc: David M. Anderson <danderso@uw.edu>

Subject: Response letter to D16-00292 (A3464-01) OLAW Case 9U

Please see attached response letter to D16-00292 (A3464-01) OLAW Case 9U.

Kim Stocking, DVM, DACLAM

Attending Veterinarian
Director, Office of Animal Welfare

Health Sciences Building Box 357160 1705 NE Pacific Street Seattle, WA 98195-7160

(b) (6)

fax<sup>(b) (6)</sup>

kstock@uw.edu/ oaw.washington.edu



#### DEPARTMENT OF HEALTH & HUMAN SERVICES

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FOR US POSTAL SERVICE DELIVERY Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500, MSC 6910 Bethesda, Maryland 20892-6910 Home Page: http://grants.nih.gov/grants/olaw/olaw.htm

FOR EXPRESS MAIL Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 Telephone: (301) 496-7163 Facsimile: (301) 402-7065

August 12, 2019

Re: Animal Welfare Assurance A3464-01 [OLAW Case 9U]

Dr. David M. Anderson **Executive Director** Health Sciences Administration University of Washington C314 Health Sciences Center, Box 356355 Seattle, WA 98195-6355

Dear Dr. Anderson,

The Office of Laboratory Animal Welfare (OLAW) has received allegations by (6) (6) of possible incidents of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Washington regarding information contained in notes from a "Harm/Benefit Assessment Subcommittee as discussed with (b) (6) It is possible that such occurrences should have been reported directly to our office as required by the PHS Policy and per your commitment to do so in your Animal Welfare Assurance.

Specifically, we request information regarding notes dated April 9, 2018 concerning "A15156 - 9 year old Indian Chinese rhesus" that was "found dead in cage cause of a large hematoma in the leg." Please provide further information on any corrective or preventive actions determined to be required by the IACUC.

Please instruct the IACUC, avoiding any conflict of interest, to send a report, signed by you as the Institutional Official, to the following OLAW email inbox: OLAWdco@od.nih.gov and provide a description of the occurrences and all corrective/preventive actions if determined to be warranted. Please have them consider if the occurrence represented programmatic failures. Please also include information regarding any PHS/NSF/DHHS funding of activities related to the occurrence, including grant or contract numbers.

We appreciate your cooperation and ask that you please provide the requested information by September 30, 2019. Please contact me if I can be of assistance at morseb@mail.nih.gov.

> Sincerely, (b)(6)

Brent C. Morse, DVM Director Division of Compliance Oversight Office of Laboratory Animal Welfare

cc: IACUC contact

# Wolff, Axel (NIH/OD) [E]

A3464-9U

From:

Wolff, Axel (NIH/OD) [E]

Sent:

Wednesday, June 26, 2019 7:02 AM

To:

(b) (6)

Subject:

RE: Documents for you to examine

(b) (6)

I have received your message and will inform you of the outcome of OLAW's investigation.

Axel Wolff, M.S., D.V.M. Deputy Director, OLAW

From: (b) (6)

Sent: Tuesday, June 25, 2019 3:34 PM

To: Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>

Subject: Documents for you to examine

Dr. Axel Wolff

Office of Laboratory Animal Welfare

Dr. Wolff,

I have come into possession of a number of records from the University of Washington, Seattle, which clearly discuss animal deaths, injuries, etc. I am certain that at least one of these incidents (the exsanguination death of a monkey following a botched blood withdrawal -- contained in the IACUC meeting minutes of 4/9/18) was not reported to OLAW, as it should have been.

These documents also discuss a number of other deaths, which are more connected to experiments, such as the death of a monkey who had a brain lesion (IACUC meeting minutes of 3/14/18), and another monkey was euthanized after implant surgery), the death of an infant at the Arizona facility, etc.

There are also a significant numbef of animal deaths of other species.

I believe that all of these incidents should have been reported to OLAW, and at least some were not.

Therefore, it is clear that your office must investigate these incidents.

A file containing all of these documents is attached to this email.

I will await your responce.

Sincerely,

(b) (6)

# Harm/Benefit Assessment Subcommittee April 9, 2018, 12:00-1:30pm, DCM Conference Room

Members present: TB, KSH, ML, JS, JPVH, JM, JB, LI, STI, CH, JI, LIE

#### Confirmation of non-quorum: Confirmed

- Category E Protocols:
  - o Gale 4158-07: Host Response to Zika Infection JPVH to present
    - Reason for consideration: May have been added to the list for possible clinical signs the mice may have (i.e., animals may potentially display clinical signs of Zika infection).
    - o Summary of Research: The primary aim of their project is to understand how viral and host factors impact innate and adaptive immune defenses to determine the outcome of virus infection. Regulatory approval to evaluate experimental drugs in humans typically requires in vivo efficacy, dose range, and dose frequency studies in vivo. The mouse is proposed as the primary species because it is sensitive to Zika Virus (ZIKV) infections, and mounts well-characterized immune responses to these viruses, which bear considerable resemblance to those in humans.
    - Purpose of Discussion: To determine if Zika infected mice need to be recategorized to E.
      - Primary aim is to study the immune defense against Zika. Mice would be a good model for this study.
      - Non-Steroidal drugs would inhibit the response readings and may interfere with results.
      - Symptoms: Hind limb paralysis, hunched posture, among other symptoms could be seen as a result of infection.
      - If animals reach a score of 6, then it should be a category E.
        - Reaching a body conditioning score of 6 is endpoint of the criteria of the protocol.
        - Endpoints are the same for all protocols. Nearly all the animals do not reach a score of 6.
      - Consider changing/adding an earlier endpoint to the protocols.
      - The group does work well to train personnel, but in genetically modified mice that are immunocompromised, the results/symptoms are uncertain and different for each strain so it will be difficult to determine a common endpoint for all strains.
    - Will ask IACUC to re-categorize Non-USDA species.
  - Dhaka 4216-01: Dhaka Mouse MB to present MOVED TO NEXT MEETING
     Reason for discussion: Unrelieved pain

- Neumaier 2950-01: Regulation of Serotonin Receptors JFI to present MOVED TO NEXT MEETING
  - Reason for discussion: Behavioral studies with noxious stimuli in mice and rats to study addiction and depression; pilocarpine-induced seizures of 1-3 hours duration.
- Buffalo
  - Reason for discussion: Lack of motivation for 2/5 days that the animal is performing for the study.
    - 25 year old Rhesus. Singly housed. Fairly new on the study 2 years on study. Her body conditioning score is 2.5 out of 5, which is not an unusual body score for an older monkey (Body conditioning scores in non-human primates are done while animals are sedated since you can't always tell the full health of the animal by just looking at it). She does have alopecia over rump, along hips and over back which make hips and spine very prominent in this animal. This can make an animal look skinnier. She is also 2 years older than the other animals on the study. Any time there is a significant change in behavior, vets are immediately contacted.
    - This animal is chaired during studies, but is eager to begin and usually completes full training, but 1 or 2 days a week doesn't complete the full allotment.
      - a. Is she getting sores, or any sort of issues from sitting in the chair for a long period of time?
      - With the alopecia along her rump may be causing her discomfort and lack of desire to perform.
    - Normally she works a couple of hours per day, and for the 1-2 days she will do less than that, but she is supplemented appropriately for lack of time. Sits on her hind feet for the most part and no rubbing has be seen. She loads herself into the chair on her own. Compared to other animals, she is the only one that doesn't completely eat all her food.
    - The criteria for removing an animal off of study is based on advice from the vet staff such as a drastic change in behavior or body conditioning score. If an animal is not working then the animal is no longer a valuable resource, but this animal is providing valuable data even on the short days.
    - a. There is an SOP on clinical endpoints in the Primate Center.
    - Animals are up on their feet and the chair is adjusted to the animal based on where they choose to sit. This animal has no issues getting in and positioning herself in the chair.
    - Only one other aged animal on study that is 2 years younger than this
      specific animal. When this specific monkey (Dorothy), came she showed
      a change in behavior which result in the vets being contacted. Her stool
      output was measured and ultimately she was put on iron supplements.

- Since iron was added, her performance has improved and has maintained since then.
- b. Weight has increased most likely due to iron supplement.
- Were arthritic changes assessed during the physical? Keith did a full work up and didn't note anything in the report.
- The alopecia makes the animal look worse than they actually are. Lack
  of motivation should be a reason to discuss this animal further. She
  does come every to work, but just doesn't work the same amount of
  time 2/5 days.
- Consider letting the animal out and move around.
- Animal is head posted in the chair so she can't move her head, but can move her body and adjust as needed.
  - She does choose not to move while working. Position doesn't seem to be correlated with the lack of motivation for those 2 days.
- If the animal were to be moved every 15 minutes, would result in an adjustment of what materials is shown and then would have to do it for all of the animals.
- The neurophysiological part of the study cannot be plugged and unplugged multiple times for removing animals.
- If she is uncomfortable and you gave her NSAIDS/pain reliever, to see if
  the pain reliever results in a change in behavior. Is there anything about
  the study that would not allow this to happen? Will check with the PI to
  see if this would cause any issues with the study.
- Have there been any patterns with the days that the study is not completed?
  - a. Mondays getting biscuits all weekend.
  - b. No other particular consistencies.
- Why is she singly housed?
  - Does not get along with any other animals, not even grooming contact. She was in a breeding colony before coming to us.
- There is no evidence that the animal is uncomfortable other than the lack of motivation on the 2/5 days. The position is the same on all days.
- Maybe she is just losing interest and not as food motivated.
- How long ago did she leave the corral?
  - a. Came in 3 years ago. Behavior did change and involved vet staff and iron supplements were added.
  - Hematocrit came back up after adding iron supplements, but protein is still kind of low. There could be an underlying medical iron.
- If she was consistently not working, then there would be more of a concern. She is currently working and providing valuable information and the behavioral data is incredibly valuable.

- Food rewards are not that varied. A new task will result in an increase or change in chow. Otherwise, the rewards are consistent because you don't want a change in behavioral data. Behavior/trainer standpoint, she does a lot very cooperatively. Very lovely animal to work with.
- Animals are allowed to work for however long they choose. Even the
  days that she is completing shorter amounts of time, the data is still
  complete regardless of time.
- LIE would like to see the data (graph) of performance over time on this
  animal
- No further discussion needed.

#### Adverse Events:

- WaNPRC:
  - o A15156 9 year old Indian Chinese rhesus. Vet was doing a pre-assignment for study. Went to draw blood, hit the femoral artery and put an ice pack on it immediately. Animal seemed to be doing okay; was on perch at the end of the day. People were checking the animal consistently until the end of the day. There was no reason to think there was any reason for further discussion. The next day, the animal was found dead in cage cause of a large hematoma in the leg. May have continued to bleed, slowly, overnight.
    - There may have been a clotting issue in the animal.
    - Also, hybridization of animals could lead to fragile vessels.
    - Animals did come in as adults and were from California.
  - a A15129 8 year old hybrid rhesus. On Buffalo neuro project with a head implant. Was previously on a study where they injected T-cells and did just fine.
    - She had a chamber implanted in February but was picking at the stiches.
    - March 12<sup>th</sup>, the animal was quiet, but active.
    - Went into Respitory distress, the animal was sedated, intubated, and IV inserted. Ultimately, she went agonal and was euthanized.
    - Necropsy showed an acute respitory event. No evidence of infectious organism. Pathologist thinks it was a weird allergic event, possibly to the antibiotics.
  - 3 Year old male pigtail that was brought up here. Animal was assigned to Ho project.
    - There are foraging devices (puzzle boards or foraging boards) that were hanging on the cages.
    - The monkey grabbed the chains of the foraging board, wrapped it around its jaw and ended up strangling itself.
    - Throat swelled up so much, which resulted in the strangulation.
    - It was a commercial device.
      - a. These were purchased with the ARC Facility.
      - b. The normal design had a spring and long chains. The device was modified to shorten the chains to there was only one lock rather than 2.

8R

- All devices (with chains) have been removed and chains over a certain length are being limited/removed completely.
- Pigtails are much more dexterous than other macaques. They utilize the enrichment differently than other non-human primates.
- Puzzle balls are outside the cage and as long as the length of the chains and how they are attached are checked.
- Other foraging boards have been used but they did not have chains.
- Paint rollers are also used for extra enrichment.
- o The cage mate was distraught after this event and was put on valium for 2 days.
- o This event has been reported to all necessary agencies (OLAW, USDA).
- o DCM:
  - o Murry project 2 pigs
    - Euthanized for a clinical endpoint. 18 days post-injection and cause may be a form of herpes (cytomygolo) virus (pig was immunosuppressed).
    - A lot better with grafts, but still struggling with immunosuppressed animals.

#### General Discussion: - Moved to Next Meeting

- A review/discussion of the Chavkin Cat E protocol that has conscious decapitations following forced swims. Question: Are there other protocols that have similar approvals?
- o Discussion of the 2-6 hours of total darkness for the animals on the neuroprotocols.

# Harm/Benefit Assessment Subcommittee May 14, 2018, 12:00-1:30pm, DCM Conference Room

Members present: TB, STI, LI, MB, JFI, JS, LJE (remote), KSH (remote), CH (remote), AB(remote)

Confirmation of non-quorum: No quorum

- · Category E Protocols:
  - Dhaka 4216-01: Dhaka Mouse -- MB to present
    - o Reason for discussion: Unrelieved pain
      - Overview of their mouse protocol is to understand the neurobiology of pain sensory systems. Their studies involve exposing mice to various types of pain. An example of one study is to induce cold sensation by injecting icilin into the hindpaw. Icilin is an agonist of the TRPM8 receptor, and it feels like menthol in creating an extreme sensation of cold. The group observes time spent flicking/lifting/licking the hindpaw over a 20 min period. They have 5 groups, 3 of which include icilin and an antagonist that would be expected to ameliorate the pain, as well as an inclin + vehicle group, which would be unmitigated pain. They also have a vehicle control group that doesn't receive any icilin. All groups are categorized as Cat E except the control group.
      - The Cat E concerns in this protocol are for Expts 4, 5, 6, 7, 8, 11, and 12, in which they perform similar studies with other pain-inducing compounds such as acetone, CFA, formalin, and capsaicin. In most of these studies, the sample size is between 60-80 mice. The animals that receive any painful compound, even with an antagonist, are classified as Cat. E while the vehicle control groups are considered Cat D.
    - o Determination: To be on the conservative side, leave animals as Cat E.
      - By doing this, the IACUC is acknowledging that there is a potential for pain and distress in these animals.
      - The group can go back and reclassify if data shows that there is no pain involved with an antagonist after giving a known pain reliever, but reclassifying animals is not necessary.

#### MB LEFT

- Adverse Events:
  - WaNPRC:
    - Update: Craniotomy a cranial implant was inserted in February. Animal was
      pulling at stitches. Seemed okay but then at the end of the day, looked tired and
      ultimately had to be euthanized due to respiratory distress.
    - There was a necropsy done that found a lesion in the brain. Lesion looks deeper in the tissue but this is likely the cause of death.
    - o PI collaborator is going to dissect the brain and gather further data.

- o Was the lesion in the area that was directly inline with the implant?
  - It was beneath the implant. It was a large implant and covered more of the skull than a usual implant.
  - Lesion is underneath the implant but there about a centimeter between implant and lesion.
  - Circle back with investigator to get histology back.
- o Z16350, a juvenile pigtail macaque in Arizona, had a fractured radius in March. Because the ulna was intact, and the fracture was not displaced, initial treatment was splinting. The splint kept slipping, so a cast was put on. The animal got the cast off, and in doing so displaced the fracture. An orthopedic surgeon was brought in to repair the fracture April 6th. Although the surgical repair was successful, the animal expired during recovery from anesthesia. Histology was non-diagnostic, suggesting an anesthetic death. Sometimes fracture repair dislodges a clot, and although no clot was seen, that could have been the cause of death.
- o DCM:

#### o Murry Pigs

- 1 pig reached experimental endpoint
- 3 pigs underwent cell injection and had been assigned shorter endpoints
  - a. 1 was euthanized at 2 weeks and the other was euthanized at 2
- 2 pigs underwent myocardial infarction and are doing well
- Pig 57718 underwent an MRI and a myocardial infarct.
  - a. Pig went into cardiac arrest and they couldn't bring it back
- o Ferrets haven't been doing any ferrets
- Puppies on childers protocol (mack), 4 puppies reached endpoint last week
   All other dogs are doing good.
- o Adopting out a rabbit
- $\circ$  Murry are starting up on Non-human primates will have to be reported once they get going

#### General Discussion:

- A review/discussion of the Chavkin Cat E protocol that has conscious decapitations following forced swims. Question: Are there other protocols that have similar approvals?
  - AVMA panel on euthanasia approves conscious decap as long as personnel are adequately trained and sharp materials.
  - Personnel are asked to provide justification. LI can figure out the number.
  - Forced swim is not an uncommon behavioral test. Mice, 6-8 protocols and some rat protocols.
  - Term conscious decapitation unanesthetized decapitation
    - Term bothered LIE
  - What are the other protocols that do this?

# Harm/Benefit Assessment Subcommittee June 11, 2018, 12:00-1:30pm, DCM Conference Room

Members present: KSH, STI, LI, JFI, JS, JB, JM, CH (remote), AB (remote), TB (in at 12:35pm)

#### Confirmation of non-quorum: Confirmed

- Category E Protocols:
  - o Fetz
- Project that does a vagal nerve cuff and then tunnel connectors under the skin and then go up and connect to the head implant.
- o Problem with the leads frequently eroding through the skin
  - Clinical Vet watched most recent surgery and found no issues with surgical technique
  - Due to erosion, these animals have frequent minor surgeries to move the leads.
  - Group was trying a nerve cuff from a different company
  - Invite the group to the next IACUC meeting for an update and invite the clinical vet to join as well.
  - Similar issue with another group, and one of the solutions was to use larger monkeys.
  - Other options to try include talking with the investigator further, considering shutting down this part of the study or
    - a. Shut down part of study or regular updates of where these projects are at
    - b. Talk with the investigator
      - i. Leads they are using are thicker than other investigators
  - Animals have undergone multiple repair surgeries.
    - a. All have had the new nerve cuff replaced.
- Two are scheduled for repair surgeries within the next week.
- KSH will contact the group and ask if any of them can come to the next IACUC meeting to give information about the project.
- Neumaier 2950-01
  - Summary of Research: This lab uses a multipronged approach to investigate
    aspects of the serotonergic system, addiction, learning, and behavior, and has
    recently joined a collaborative effort to examine epilepsy. Mice and rats are
    used in these studies. Some of the studies involve behavioral testing that aims
    to model depression.
  - Purpose of Discussion: To determine if current categorizations are correct, and review other behavioral tests that involve noxious stimuli.
  - o Notes:

- Document in SharePoint with additional details: procedures including those that are listed as Cat E and those that are not but should be considered Cat E.
  - a. Those currently listed as Cat E will remain as Cat E.
  - b. Mice: Currently not Cat E, but involves shock
    - i. Neumaler-Mouse: Fear Conditioning
      - This procedure is inescapable, however the shock is a brief at 0.5-0.9 mA.
      - If it is no worse than a ketamine injection, than it shouldn't be considered Cat E.
      - 3. Not going to categorized Cat E.
    - ii. Neumaier-Mouse: Predator Stress -
      - This procedure does cause stress, but not necessarily distressful and there is no pain. Will not be Cat E.
    - iii. Neumaier-Mouse: Social Defeat and V.2
      - These will not considered Cat E since they take the necessary precautions to avoid undo harm to the animals.
  - c. Rats: Currently not Cat E, but involves shock
    - i. All left as not Cat E.

#### TB entered.

- Current amendment in process:
  - Morphine addicted animals and undergo withdrawal symptoms in mice results in the mice looking constantly sick so it is difficult to determine an endpoint, however the animals don't usually die.
  - b. Give naloxone to stimulate withdrawal and the animals are scored for up to 12 hours in the lab and then recover.
  - Consider talking with an MD who treats addicts for additional information such as Dr. Susan Stern.
    - JFI to reach out to Dr. Stern for more information on withdrawal symptoms and related mortality.
- Adverse Events:
  - o WaNPRC:
    - o Clinical
      - 1 spontaneous death
        - Squirrel monkey that was almost 19 years old that died in its sleep in a hammock.
          - May have been due to a large heart, but hard to tell.
             Could also be due to old age.

- A couple of Kiem animals had to be euthanized. Waiting for necropsies for these animals.
- An animal that bloated and KV decompressed. Animal looked fine, but while bloated it developed a small perforation and ultimately had to be outbasized.

o Dorothy

- No update on her yet.
- o DCM:
  - Murry: 2 pigs on study (both had received MRI, myocardial infarcts, and injections)
    - 1 of them is doing well
    - Other reported diahrrea and blood in urine
      - a. Rapid decline and was ultimately euthanized.
      - b. Not completely clear what cause the decline.
      - c. Was on antivirals, which was used successfully in a few pigs.
    - Atrial scar model
      - a. One pig undergoing this
      - b. Planned experimental endpoint is July 9th

o Mack:

- Several puppies (9-10 months old) recently came to their endpoints.
- There were no complications, and everything went well, but has been a tough time for DCM staff.
- Everything is going well with the dogs.
- 2 puppies were born 16 days ago and are muscular dystrophy dogs (Tank and Hummer). Hummer is being tube fed around the clock.
  - University of Texas has said that if you can get them past 3 weeks, then often their suckling will develop.
- 1 more dog that is currently pregnant with what looks to be only one puppy.
- o No Sheep.
- o Ferrets starting up.
- General Discussion:
  - McGuire going to FCR.
    - PI has not done any work with monkeys in the past.
    - Many IACUC members were concerned.
      - Identifying infected animals as quickly as possible so the animals can go back to social housing as quickly as possible.
      - Singly housed for a maximum 10 weeks, with blood draws occurring once a week. Blood draws will be analyzed for antibodies and PCR.
        - Once animals are identified as positive, animals can be housed together.
      - Animals are sedated during blood draws and blood is analyzed promptly once a week.

#### • Adverse Events:

- o WaNPRC:
  - o June, there was one spontaneous death of an infant in Arizona. The necropsy did not show any results and still waiting on the histo.
  - o There were 2 Kean animals that had to be euthanized early.
    - 7/8, a Kean animal died spontaneously.
    - Waiting on histo for these animals as well.
- o DCM:
  - $\circ$  1 more muscular dystrophy puppy was born and is doing well. This puppy is affected and currently being tube fed.

#### General Discussion:

- Concerns raised regarding monkeys that are in restraint chairs for multiple hours per day.
  - Currently do not have the necessary equipment to study bone density.
  - There could be issues as a result of extended restraint such as muscle atrophy.
     The animals do get physical examinations twice a year.
  - Currently, there is no sign of muscle atrophy or increase in arthritic changes.
  - The occurrence of arthritic issues and muscle atrophy is higher however, in animals that have a sedentary lifestyle.
  - Could reach out to those who specialize in bone changes.
- o Dr. Stern is able to come present to the IACUC possibly in September.
- o "Dorothy"
  - There was an attempt to socially house her. It was a bad experience and as a result of this, she stopped eating. Dorothy never recovered and was ultimately euthanized.

# Harm/Benefit Assessment Subcommittee July 9, 2018, 12:00-1:30pm, DCM Conference Room

#### Members present: JS, LJE, KSH, JFI, STI (remote), KS (remote), LI, JE, CH (remote), TB

#### Confirmation of non-quorum: Confirmed

- Category E Protocols:
  - Amendment for Kaeberlein 4359-03: Pharmacological and Genetic Approaches to Mitochondrial Disease – LJE to present
    - Main purpose of methods to treat laisse syndrome. They focus on a drug called Rapamycin. Rapamycin alters several metabolic processes and has multiple side effects.
      - Effects vary depending on dosage.
    - o Rapamycin is currently used, but for a different purpose in humans.
    - o On this protocol, all but 2 experiments contain Cat E animals.
    - The main purpose is to measure extension of lifespan and therefore their criteria for euthanasia is beyond what is usually done.
    - Mice are observed on a daily basis and rather than a typical 20% loss before euthanasia, they have a loss of 30% loss (severely moribund) before euthanasia approved on their protocol.
      - Typically, an extension to greater than 20% weight loss is allowed because animals have lost greater than 20% and recovered.
      - There was extensive discussion regarding this protocol before the Harm Benefit subcommittee was active.
        - There are other factors, other than weight loss, that can be used as predictors of the animal welfare.
    - o The Triennial of this protocol was reviewed November 2017.
    - It is not the current policy to send Cat E directly to FCR. The IACUC can consider changing this.
    - Weight is not necessarily the best criteria depending on the model. 20%, is an arbitrary number because there are animals that have 20% weight loss, but a normal body condition.
    - With the animals involved in the study, they are under stress from early on, so they compensate for it and as a result, weight loss may not be the best indicator of death for these animals.
    - a Currently, they use observational methods to determine condition of animals.
    - Mortality is actively tracked by vet services, but they do not come up commonly with unexpected mortality rates.
    - The group does the best they can to ensure the animals undergo as little pain and stress as they can.
  - For protocols that a member would like to call for FCR in between regular review, there should be a different term used other than FCR.
    - o Work to come up with a different label for these types of protocols.



DFORBES

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# **Inspection Report**

University Of Washington

Box 357160

Seattle, WA 98195

Customer ID: 1016

Certificate: 91-R-0001

Site: 001

UNIVERSITY OF WASHINGTON

Type: ROUTINE INSPECTION

Date: 04-JUN-2019

## 2.33(b)(2)

#### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

There was an incident of diversion of a controlled substance that led to one nonhuman primate possibly receiving less than the optimum dosing of an opioid analgesic during clinical treatment. After the diversion was discovered, the drug vial was analyzed and the drug was found to have been diluted. The animal did receive other pain relievers and did not appear clinically painful during that time and recovered uneventfully.

The use of appropriate methods to treat diseases and injuries must be used and maintained to ensure animal welfare. The employee involved in the incident has been terminated from employment. This drug has been transferred to a central safe with limited access and is not in the lock box at the individual facilities. If an animal needs the medication, aliquots are taken out to do the treatment. The research facility had instituted corrective actions prior to this inspection.

During the inspection, a controlled drug cabinet was found open and unattended with the key in the lock. The research facility has taken corrective actions for this issue. The principal investigator of the lab with the open drug cabinet has placed a reminder sign on the procedure room door where the drug cabinet is located, and reassigned the individual responsible for controlled substances in the lab. Completed as of 6/10/19.

In addition, the research facility will reiterate the expectation that all researchers must keep their controlled substances secure at all times. The Office of Animal Welfare (OAW) will also send out a communication to researchers about this expectation by 6/14/19. Additional periodic reminder communications will come through OAW's July newsletter, on-going OAW staff interactions with researchers and during IACUC semi-annual inspections. Facility staff have also been instructed to report to their supervisors any drug cabinets found unsecured.

Prepared By: FORBES DIANE, D V M

FORBES DIANE, D V M USDA, APHIS, Animal Care

VETERINARY MEDICAL OFFICER 5053

Received By:

Title:

Title:

**Date:** 19-JUN-2019

**Date:** 19-JUN-2019



**DFORBES** 

2016082569505833 Insp\_id

# **Inspection Report**

# 2.33(b)(5) CRITICAL

## ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

On protocol #2225-06, a nonhuman primate underwent surgery and died during the recovery period. On the morning of the surgery, it was found that the animal had not been fasted due to a miscommunication. The veterinary surgical teams agreed to delay the procedure for over one hour (an abbreviated fast) and then proceeded. The surgery was uneventful; however, the animal went into respiratory arrest during the recovery period which lead to the need for CPR and re-intubation. During CPR, the animal was seen to vomit, and ingesta was aspirated. The animal was revived and appeared to be recovering, but arrested again later and died. Based on the clinical course, laryngospasm was postulated as the cause of death and aspiration of food may have been a contributing factor.

Each research facility must establish and maintain programs of adequate veterinary care that include pre-procedural and post-procedural care in accordance with established veterinary medical and nursing care. Both the protocol and the facility's SOP require that the day prior to the performance of the procedure, animals will be fasted after their morning feeding for a minimum of 12 hours.

The research facility had instituted corrective actions prior to this inspection. The facility SOP is being revised to include if an animal has not been fasted appropriately, the research procedure will be rescheduled. The only exceptions would be in an emergency or clinical case, and must be approved by the Attending Veterinarian or the Associate Director, Department of Primate Resources.

Inspection was conducted from June 4 - 6, 2019.

This inspection and exit briefing were conducted with the facility representatives.

# **Additional Inspectors**

Schnell Michael, Supervisory Animal Care Specialist

Prepared By: FORBES DIANE, D V M

FORBES DIANE, D V M USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER 5053

Page 19-JUN-2019

Date: 19-JUN-2019



001343

Total

United States Department of Agriculture Animal and Plant Health Inspection Service

Customer: 1016
Inspection Date: 04-JUN-19

# **Species Inspected**

Cust No	Cert No	Site	Site Name	Inspection	
1016	91-R-0001	001	UNIVERSITY OF WASHINGTON	04-JUN-19	
Count	Scientific Name		Common Name		
000017	Canis lupus familia	aris	DOG ADULT		
000026	Macaca fasciculari	is .	CRAB-EATING MACAQU	E / CYNOMOLGUS MONKEY	
000228	Macaca mulatta		RHESUS MACAQUE		
000972	Macaca nemestrin	а	PIG-TAILED MACAQUE		
000029	Mustela putorius fu	ıro	DOMESTIC FERRET		
000048	Oryctolagus cunicu	ulus	DOMESTIC RABBIT / EU	ROPEAN RABBIT	
000013	Saimiri sciureus		COMMON SQUIRREL MO	ONKEY	
000010	0 Sus scrofa domestica		DOMESTIC PIG / POTBE	DOMESTIC PIG / POTBELLY PIG / MICRO PIG	



DFORBES

2016082569328955 Insp\_id

# **Inspection Report**

University Of Washington

Box 357160

Seattle, WA 98195

Customer ID: 1016

Certificate: 91-R-0001

Site: 001

UNIVERSITY OF WASHINGTON

Type: FOCUSED INSPECTION

Date: 15-NOV-2018

# 2.38(f)(1) CRITICAL

#### MISCELLANEOUS.

A pigtail macaque pulled a chain holding an enrichment device into the cage, entangled its jaw, and asphyxiated. These types of enrichment devices were being modified to fit better, and the one involved had not been properly installed.

The facility self-reported the incident to APHIS officials. The corrective actions consisted of promptly removing all of the foraging/enrichment devices from all cages and returning to the use of puzzle balls. To prevent a similar incident in the future, all enrichment devices will be evaluated by a committee before being used with animals.

Correct from this time forward.

This inspection and exit briefing were conducted with the facility representatives.

# **Additional Inspectors**

Schnell Michael, Veterinary Medical Officer

Prepared By: FORBES DIANE, D V M

FORBES DIANE, D V M USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER 5053

Received By:

Date:

16-NOV-2018

Date:



Customer: 1016
Inspection Date: 15-NOV-18

# **Species Inspected**

Cust No	Cert No	Site	Site Name	Inspection		
1016	91-R-0001	001	UNIVERSITY OF WASHINGTON	15-NOV-18		
No Animals were Inspected.						

 Count
 Scientific Name
 Common Name

 000000
 NONE
 NONE

 000000
 Total
 NONE



THOMPSON 264091422050098 insp id

#### Inspection Report

UNIVERSITY OF WASHINGTON

Customer ID: 1016

Certificate: 91-R-0001

Site: 001

BOX 357190 UNIVERSITY OF WASHINGTON

Type: ROUTINE INSPECTION

Date: Sep-17-2009

SEATTLE, WA 98195

2.33 (b) (2)

#### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

<<Each research facility shall establish and maintain programs of adequate veterinary care that include: The use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care;>>

During the inspection, four vials of Hydromorphone, stored in the drug box in the surgery area for nonhuman primates, were found to have expired as of 5/09. An syringe filled with a fluid which was not identified was found in a drug box in the nonhuman primate facility. Use of unlabeled and expired medical materials are not considered to be adequate veterinary care since the desired effect may not be predictable and therefore may not relieve the animal's pain and/or distress.

Programs of veterinary care shall include appropriate methods to prevent, control, diagnose, and treat diseases and injuries.

Corrected on site.

#### 2.33

#### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

<Each research facility shall establish and maintain programs of adequate veterinary care that include: Daily observation of all animals to assess their health and well-being; Provided, however, That daily observation of animals may be accomplished by someone other than the attending veterinarian; and Provided, further, That a mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian;>>

During a review of the facility's records, it was noted that a 3.5 year old male nonhuman primate had been found dead due to malnutrition with a resulting 25% loss of body weight. The animal had been introduced into a new group of conspecific animals and was being observed daily by the staff for any signs of aggression from the group. The

Prepared By:

TRACY A THOMPSON, D.V.M. USDA, APHIS, Animal Care
VETERINARY MEDICAL OFFICER Inspector 5044

Received By:

(b)(6),(b)(7)(c)

Page 1 of 3

Guillermo Decl. Exhibit B Page 32 of 38

Date:

Date:

Sep-21-2009

Sep-21-2009



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#### Inspection Report

facility has a protocol for collection of weights on the primates at least monthly but this animal had not been weighed for greater than 2 months prior to his death. This mechanism of monthly weights may have allowed the staff to recognize the animal's loss of body condition in a timely manner in order to prevent his death.

A mechanism of direct and frequent communication is required so that timely and accurate information on an animal's health and well-being may be conveyed to the Attending Veterinarian.

The facility has instituted a more strict mechanism of identifying animals which are overdue for monthly weight collection.

Corrected.

3.75 (e)

#### HOUSING FACILITIES, GENERAL.

<<Storage...Food requiring refrigeration must be stored accordingly, and all food must be stored in a manner that prevents contamination and deterioration of its nutritive value.>>

The shelves of the refrigerator in the Veterinary Services area for the second floor unit of nonhuman primate housing were soiled and had a buildup of food debris. A bunch of bananas and 1/2 of a yam were stored in this refrigerator purportedly for use by the Psychological Well-Being (PWB) staff for environmental enhancement for some of the primates. This food was not stored such that it was protected from contamination or deterioration.

All food must be store in a manner that prevents contamination and deterioration of its nutritive value.

To be corrected by 9/24/09.

3.80 (a) (2) (xi)

#### PRIMARY ENCLOSURES.

<< Primary enclosures must be constructed and maintained so that they: Provide sufficient space for the nonhuman primates to make normal postural adjustments with freedom of movement.>>

During the inspection, two adult male baboons with cranial implants were noted to be unable to sit upright in a normal manner when on the perch in their primary enclosure due to the height of the implant.

Primary enclosures must provide sufficient space for the nonhuman primates to make normal postural adjustments.

To be corrected by 9/24/09.

Prepared By:

TRACY A THOMPSON, D.V.M. USDA, APHIS, Animal Care

VETERINARY MEDICAL OFFICER Inspector 5044

Received By:

(b)(6),(b)(7)(c)

Title:

Page 2 of 3

Guillermo Decl. Exhibit B Page 33 of 38

Date:

Date:

Sep-21-2009

Sep-21-2009



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## Inspection Report

Inspection performed 9/15-17/09. Accompanied on inspection by the Director, Office of Animal Welfare, the Associate Director for Research Resources, the Occupational Health and Biosafety Coordinator, several Animal Technicians, several Husbandry and Animal Tech Supervisors, several Veterinary Services personnel, the Assistant Director, Husbandry Unit, Program Coordinators, a PWB Technician, the Decentralized Facilities Program Coordinator, and a Laboratory Technician.

Prepared By:

TRACY A THOMPSON, D.V.M. USDA, APHIS, Animal Care

VETERINARY MEDICAL OFFICER Inspector 5044

Received By:

(b)(6),(b)(7)(c)

Title:

Page 3 of 3

Date:

Sep-21-2009

Sep-21-2009

Date:



DFORBES

2016082568076822 Insp\_id

# **Inspection Report**

University Of Washington

Box 357160

Seattle, WA 98195

Customer ID: 1016

Certificate: 91-R-0001

Site: 001

UNIVERSITY OF WASHINGTON

Type: ROUTINE INSPECTION

Date: 25-JAN-2017

## 3.83 CRITICAL

#### WATERING.

The research facility self-reported an adverse event that occurred on 08 JAN 17 involving the death of a nonhuman primate. While performing unrelated rounds and treatments, a veterinary technician found an eight-year-old pigtail macaque that was lethargic, and contacted the veterinarian on call. The veterinarian determined that the animal was severely dehydrated. The water line to the cage was not connected. Veterinary treatment was initiated, however, the animal later died during treatment. Animal husbandry logs indicated that twice daily lixit checks had been performed every day prior to the incident to ensure the lixits were functioning properly and food consumption logs had been normal. However, the clinical condition and necropsy findings were consistent with the animal not having water for at least 48-72 hours. No other animals were affected.

The research facility initiated corrective actions prior to this inspection including completion of documented retraining of care staff, initiating disciplinary action for the involved employee, and revision of their policy such that any schedule changes for husbandry activities like cage cleaning rotation must be approved by a veterinarian instead of the supervisor. Additionally, the Institutional Animal Care and Use Committee (IACUC) reviewed the events and issued a letter of reprimand to the affected facility; the IACUC will be further investigating this incident at the next scheduled meeting. The facility will also be establishing a process for annual re-certification of animal care staff and incorporate that into their standard operating procedures.

The provision of potable water and reliable processes to assure such provision are absolutely critical and fundamental to the health and well-being of animals. The facility must assure that employees are trained and effectively complete critical care tasks, including re-certification of animal care employees.

Correct from this time forward.

## 3.84(b)(2)

Prepared By:

DIANE FORBES, D V M

DIANE FORBES USDA, APHIS, Animal Care 26-JAN-2017

Title: VETERINARY MEDICAL OFFICER 5053

Received By:

Date: 26-JAN-2017

Page 1 of 2



**DFORBES** 

2016082568076822 Insp\_id

# **Inspection Report**

#### CLEANING, SANITIZATION, HOUSEKEEPING, AND PEST CONTROL.

The research facility self-reported that the cages housing six nonhuman primates, which included the animal that died on 08 January 2017, had not been changed or sanitized for 17 days prior to the adverse event that contributed to the death of the pigtail macaque. Instead of completing the scheduled regular sanitization on 06 January 2017, the immediate area supervisor had decided to wait until 09 January 2017 for a scheduled specialized sanitization process. Had the affected animal's cage been changed within the required two week period, the disconnected water line would have been discovered by facility staff, thus averting the incident.

Completion of regularly scheduled sanitization of cages at a frequency of at least once every 2 weeks is necessary for the health and well-being of the animals.

The research facility had instituted corrective actions prior to the inspection including retraining of the supervisory and care staff and revision of their policy such that any schedule changes for husbandry activities like cage cleaning rotation must be approved by a veterinarian instead of the supervisor. The facility will also be establishing a process for annual re-certification of animal care staff and incorporate that into their standard operating procedures.

Correct standard operating procedure by 28 February 2017.

This inspection and exit briefing were conducted with the facility representatives.

#### **Additional Inspectors**

Michael Schnell, Veterinary Medical Officer

DIANE FORBES, D V M Prepared By: Date: DIANE FORBES USDA, APHIS, Animal Care 26-JAN-2017 VETERINARY MEDICAL OFFICER 5053 Title: Received By: Date: 26-JAN-2017 Title:



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# Inspection Report

University Of Washington Box 357160 Seattle, WA 98195

Customer ID: 1016
Certificate: 91-R-0001

Site: 002

UNIVERSITY OF WASHINGTON

Type: ROUTINE INSPECTION

Date: Aug-01-2014

2.33 (b) (2)

#### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

\*\*\*On May 2, 2013, a 1-month old male pig-tailed macaque (ID #Z13068) along with its mother, were introduced to their assigned breeding group following a 2 day protected contact period when the infant was attacked. Approximately 15-20 minutes after open contact was established, the single adult male of the group attacked the infant. The infant sustained extensive trauma and was euthanized by the veterinarian.

In a separate breeding group, on May 30, 2013, a 6-month old male pig-tailed macaque (ID #Z13080), was attacked by the adult male in its group. That animal (ID #Z13080), subsequently died from its injuries. In another separate incident on June 12, 2013, a 9-month old female pig-tailed macaque (ID #Z12341) was attacked by an adult male, through mesh contact and was euthanized by the veterinarian.

Following the May 2nd attack, the veterinarian notified the facility behavioral management group of the incident. The veterinarian and the behavioral group also discussed the temperament and behavioral history of the male that was involved in the May 2nd attack. There were no subsequent dam/infant pairs placed with the male involved in the May 2nd attack. Following the May 30th attack, all males were removed from breeding groups until new group assignments and behavioral assessments were complete. Mesh contact remained following the May 30th attack, as to not completely disrupt the groups.

It is common for males, including male primates, to attack and kill young offspring of their species (known as infanticide). Knowing this behavior (as stated by the facility) and that it was occurring at the facility, it is the veterinarian's and the facility's responsibility to prevent this behavior and any subsequent injuries. Preventative action should have been taken following the May 2nd attack, before the attacks on May 30th and June 12th. The facility has implemented changes in their group housing policy. After June 12, 2013, young primates are no longer housed with adult males, in order to prevent future attacks.

An inspection was started on 7/14/14 and finished on 8/1/14 to review animal enclosures and animal medical records.

 AARON RHYNER, V M O

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 USDA, APHIS, Animal Care
 Date:

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 VETERINARY MEDICAL OFFICER Inspector 6077
 Feb-11-2015

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Inspection Report Explanation: http://www.aphis.usda.gov/animal\_welfare/downloads/IR\_Explanation.pdf



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# Inspection Report

Exit interview was conducted on-site with the veterinarian on 8/7/14.

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